Remarks

Claims 1-12 were pending in the subject application. By this Amendment, claims 1, 4, 7, 8, and 11 have been amended. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-12 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

The applicant gratefully acknowledges the Examiner's indication that claims 7, 8, and 12 are allowable in the subject application.

In response to the Examiner's indication that the specification is not in compliance with the sequence rules, submitted herewith is a copy of the Amendment submitted in the subject application on October 30, 2002 in reply to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosure dated October 2, 2002. Appropriate numeric sequence identifiers were added to the specification by this Amendment. Also submitted herewith is a return-receipt postcard verifying that the Amendment was submitted on October 30, 2002 and received by the Patent Office. The applicant respectfully requests that the Amendment of October 30, 2002 be entered in the subject application. Reconsideration and withdrawal of the objection to the specification is respectfully requested.

Also enclosed herewith are copies of those references listed on the PTO/SB/08 form that accompanied the Information Disclosure Statement of June 19, 2003, which were not considered by the Examiner. Acknowledgment of their consideration by the Examiner is respectfully requested.

Also submitted herewith is a copy of a supplemental Information Disclosure Statement with form PTO/SB/08 submitted on August 25, 2003 and a copy of the return receipt postcard verifying its receipt by the Patent Office. The applicant respectfully requests that the references listed in the supplemental Information Disclosure Statement be considered by the Examiner and that such consideration be acknowledged and made of record in the subject application.

Claims 4-6, 9, and 10 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite. The applicant respectfully submits that the claims are not indefinite. However, the applicant has amended the claims solely in the interest of facilitating prosecution. Specifically, claim

1 has been amended to recite that the nucleic acid encodes an immunogenic peptide, which clarifies that the encoding of an additional immunogenic peptide is intended in claim 4. In addition, claims 7 and 8 have been amended to recite, respectively, "an immunogenic peptide" and "an additional immunogenic peptide", thereby providing clear antecedent basis for claims 9 and 10. Support for these amendments can be found, for example, at pages 17-19 and 26-27 of the subject specification. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

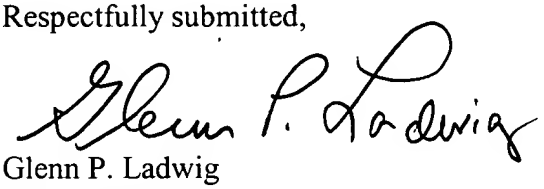
Claims 1-6 and 11 have been rejected under 35 U.S.C. §112, first paragraph, as lacking sufficient written description. The applicant respectfully submits that the subject specification reasonably conveys to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. However, by this Amendment, the applicant has amended claims 1 and 11 to recite functional characteristics similar to those suggested by the Examiner at page 4 of the Office Action. Specifically, claims 1 and 11 recite that the peptide, or a fragment thereof, binds to an appropriate HLA molecule to form a complex recognized by cytotoxic T cells which T cells recognize a native HBV antigen. Support for this amendment can be found, for example, at page 7, lines 33-38, page 8, lines 1-7, and page 14, lines 11-36, of the subject specification. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Glenn P. Ladwig
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Fax No.: 352-372-5800
Address: Saliwanchik, Lloyd & Saliwanchik
A Professional Association
2421 NW 41st Street, Suite A-1
Gainesville, FL 32606-6669

GPL/mv

Attachments: Copy of Amendment submitted on October 30, 2002 and return receipt postcard evidencing same;
Copy of supplemental Information Disclosure Statement, including form PTO/SB/08, submitted on August 25, 2003 and return receipt postcard evidencing same; and
Copies of:
JP 60-161999
Deres *et al.* (1989)
Rotzschke *et al.* (1990)
Bertoletti *et al.* (1991)
Penna *et al.* (1992)

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Arlington, VA 22202

On 30 Oct. 2002

TOWNSEND and TOWNSEND and CREW LLP

By: Malinda Dogit

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PATENT
Attorney Docket No.: 014740-000421US
Client Ref. No.: 0242.2 C1 D1 - emp
0035P EPI 2242.2

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CHISARI, Francis V.

Application No.: 09/863,054

Filed: May 21, 2001

For: PEPTIDES FOR INDUCING CYTOTOXIC T LYMPHOCYTE RESPONSES TO HEPATITIS B VIRUS

Examiner: Wortman, Donna C.

Art Unit: 1648

COMMUNICATION UNDER

37 C.F.R. §§ 1.821-1.825

AND

AMENDMENT

U.S. Patent and Trademark Office
Box SEQUENCE
P.O. Box 2327
Arlington, VA 22202

Sir:

In response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, 37 C.F.R. §§ 1.821-1.825, that accompanied the Office Communication mailed October 2, 2002, Applicants submit herewith the required paper copy and computer readable copy of the Substitute Sequence Listing. Please amend the specification in adherence with 37 C.F.R. §§ 1.821-1.825 as follows.

In the Specification:

Please replace the paragraph beginning at page 5, line 22, with the following:

--Fig. 1 shows that HBsAg335-343, WLSLLVPFV (SEQ ID NO:10), is the minimal optimal CTL epitope recognized by CTL stimulated HBsAg329-348. A CTL clone from patient A-1 and a CTL cloned line from patient A-3, generated by stimulation with HBsAg329-348, were tested against JY target celss prepulsed either with truncations (SEQ ID NOS:22 and 28-39, respectively) (upper panels) or with overlapping 9-mers or 10-mers (SEQ ID NOS:22, 40-50, 15, 10, 16, 51-55, 25, 56, 38 and 39, respectively) (lower lowers panels) covering HBsAg329-348.--

Please replace the paragraph beginning at page 5, line 29, with the following:

--Fig. 2 further confirms that an optimal epitope within HBsAg329-348 for in vitro CTL indusction is HBsAg335-343 (SEQ ID NOS:22, 53, 52, 10, 51, 50 and 25, respectively).--

Please replace the paragraph beginning at page 6, line 3, with the following:

--Fig. 4 shows the results of HLA-A2.1 competitive binding inhibition assays (SEQ ID NOS:24,7, 9, 10, 25, 26 and 27, respectively), represented as % inhibition of HBcAg18-27 specific lysis in a 4 hour ^{51}Cr release assay.--

Please replace the paragraph beginning at page 33, line 23, with the following:

--Two HLA-A2 positive patients with acute hepatitis (A-1 and A-3) wereinitially selected for analysis of the CTL response to HbsAg329-348 (ASARFSWLSLLVPFVQWFVG (SEQ ID NO:22)), which contains 2 overlapping HLA

a2.1 allele specific binding motifs (WLSLLVPFV (SEQ ID NO:10) and LLVPFVQWFV (SEQ ID NO:25)). One of these patients (A-3) was known from previous experiments to display an HLA A2 restricted CTL response to a 10 residue HBV nucleocapsid epitope (HBcAg18-27) that also represents an HLA A2.1 allele specific binding motif (FLPSDFFPSV (SEQ ID NO:23)). This patient was considered a potential responder to one or both of the motifs in HBsAg329-348. Another patient (A-1), known to be a nonresponder to HBsAg18-27, was studied for comparison.--

Please replace the paragraph beginning at page 35, line 6, with the following:

--The results, shown in Fig. 1, indicated that only the first of the HLA-A2.1 binding motifs (HBsAg335-343) is recognized by the CTL. Furthermore, the data demonstrate that this peptide (WLSLLVPFV (SEQ ID NO:10)) is the minimal, optimal HLA-A2 restricted epitope recognized by HBsAg329-348 stimulated CTL, since omission of the extreme amino-terminal or the extreme carboxy-terminal residue from HBsAg335-343 abolishes recognition by the CTL.--

Please replace the paragraph beginning at page 37, line 22, with the following:

--Nucleotide sequence analysis of circulating virion DNA in acutely infected patients showed that all patients, including the CTL nonresponders, were infected by viruses that expressed the precise amino acid sequence present in the prototype HBsAg335-343 peptide used to stimulate expansion of CTL in vitro. Since residues 335-343 are known to be conserved in all the published HBV sequences derived from all 4 HBV subtypes, as published in the GenBank-72 database, as well as in the 10 patients studied herein, it may be concluded that HBsAg335-343 is an HBV group specific CTL epitope. The same was not true for HBsAg348-357, however, since only seven of the ten patients were found to be infected by viruses that encode the prototype sequence used for in vitro stimulation (GLSPTVWLSV (SEQ ID NO:26)). The

remaining three patients (A-9, A-10, A-13) displayed a variant sequence in which the carboxy-terminal valine was substituted by alanine at position 357. Among the patients infected by the prototype virus, CTL responders and nonresponders to HBsAg348-357 were observed, just as for the response to BsAg335-343. On the other hand, none of the 3 patients infected by the variant virus displayed a CTL response to the prototype peptide.--

Please replace the paragraph beginning at page 40, line 26, with the following:

--An $HBsAg_{335-343}$ specific CTL line (patient A-1) and an $HBsAg_{348-357}$ specific CTL line (patient A-4) were generated by stimulation with peptide sequences WLSLLVPFV (SEQ ID NO:10) and GLSPTVWLSV (SEQ ID NO:26), respectively. CTL were incubated with ^{51}Cr-labelled JY target cells that had been preincubated either with media, with the inducing peptide or (in the case of $HBsAg_{348-357}$) with a variant peptide (GLSPTVWLSA (SEQ ID NO:57)). CTL were also incubated with ^{51}Cr-labelled JY target cells that had been infected with a panel of 6 recombinant vaccinia viruses that express the HBV major (V-HBs), middle (V-preS2), and large (V-preS1) envelope polypeptides derived from ayw and adw HBV genomes. Wild-type vaccinia viruses (V-wt) were used as controls. The $HBsAg_{335-343}$ specific CTL line (right panel) was used at an E:T=40:1. The $HBsAg_{348-357}$ specific CTL line (left panel) was used at an E:T=3:1. Results shown represent % lysis in a 4 hour ^{51}Cr release assay.--

Please cancel the present "SEQUENCE LISTING", pages 42-49, and insert therefor the accompanying paper copy of the Substitute Sequence Listing, page numbers 1 to 18, at the end of the application. Cancel the page numbers for the Claims and Abstract and renumber as pages 42-44, accordingly.

REMARKS

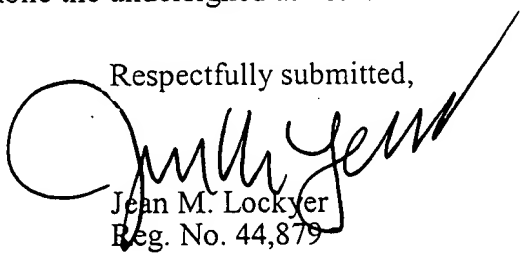
Applicants request entry of this amendment in adherence with 37 C.F.R. §§1.821 to 1.825. This amendment is accompanied by a floppy disk containing the above named sequences, SEQ ID NOS:1-57, in computer readable form, and a paper copy of the sequence information which has been printed from the floppy disk.

The information contained in the computer readable disk was prepared through the use of the software program "PatentIn" and is identical to that of the paper copy. This amendment contains no new matter.

Attached hereto is a marked-up version of the changes made to the Specification by the current Amendment. The attached pages are captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Jean M. Lockyer
Reg. No. 44,879

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
JML:dmw
SF 1400876 v1

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph beginning at line 22 of page 5 has been amended as follows:

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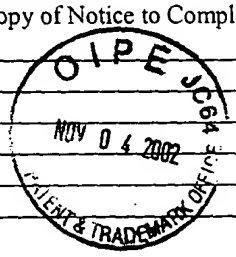
Please stamp the date of receipt of the following document(s) and return this card to us:

INVENTOR(S):	Francis V. Chisari
RE:	PATENT APPLICATION FILED 5/21/01 FOR "PEPTIDES FOR INDUCING CYTOTOXIC T LYMPHOCYTE RESPONSES TO HEPATITIS B VIRUS"
TITLE OF DOCUMENT(S):	Communication Under 37 CFR 1.821-1.825 and Amendment; Sequence Listing paper copy pages 1-18; Sequence Listing diskette copy; copy of Notice to Comply Transmittal Form PTO/SB 21;
Application No.	09/863,054
File No.	14740-0004-21
Date Due	2 Nov. 2002
Date Mailed	30 Oct. 2002
Attorney/Secretary	JML/mcd



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on August 25, 2003

Glenn P. Ladwig

Glenn P. Ladwig, Patent Attorney

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
Examining Group 1648
Patent Application
Docket No. EPI-T101D4
Serial No. 09/863,054

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Donna C. Wortman
Art Unit	:	1648
Applicant	:	Francis V. Chisari
Serial No.	:	09/863,054
Filed	:	May 21, 2001
For	:	Peptides for Inducing Cytotoxic T Lymphocyte Responses to Hepatitis B Virus

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

The applicant respectfully asserts that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Glenn P. Ladwig

COPY

Glenn P. Ladwig
Patent Attorney
Registration No. 46,853
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

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Attachments: Form PTO/SB/08 (2 page); copies of references cited therein.

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PTO/SB/08A (08-00)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	09/863,054
Filing Date	May 21, 2001
First Named Inventor	Francis V. Chisari
Group Art Unit	1648
Examiner Name	Donna C. Wortman
Attorney Docket Number	EPI-T101D4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. [1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	5,780,036		Chisari	07-14-1998	All
	U2	6,322,789	B1	Vltiello et al.	11-27-2001	All
	U3					
	U4					
	U5					
	U6					
	U7					
	U8					
	U9					
	U10					
	U11					
	U12					
	U13					
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	F1	WO	94/20127	A1	Cytel Corp.	09-15-1994	All	
	F2	WO	94/25060	A1	Ladd et al.	11-10-1994	All	
	F3	WO	95/04817	A1	Cytel Corp.	02-16-1995	All	
	F4	WO	92/00753	A1	Regents of Univ. of Calif.	01-23-1992	All	
	F5	WO	94/03205	A1	Cytel Corp.	02-17-1994		
	F6	EP	327369	A2	Regents of Univ. of Calif.	08-09-1989	All	
	F7							
	F8							

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	09/863,054
Filing Date	May 21, 2001
First Named Inventor	Francis V. Chisari
Group Art Unit	1648
Examiner Name	Donna C. Wortman
Attorney Docket Number	EPI-T101D4

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. [1]	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
	R1	CARBONE, F.R. and M.J. BEVAN "Induction of Ovalbumin-Specific Cytotoxic T Cells by In Vivo Peptide Immunization" *J. Exp. Med.*, March 1989, 169:603-612.	
	R2	COLLINS, D.S. *et al.* "Processing of Exogenous Liposome-Encapsulated Antigens In Vivo Generates Class I MHC-Restricted T Cell Response" *J. Immunology*, 1992, 148:3336-3341.	
	R3	LEE, K.K. *et al.* "Cross-Reactive and Strain-Specific Antipeptide Antibodies to *Pseudomonas aeruginosa* PAK and PAO Pili" *Infection and Immunity*, September 1990, 58(9):2727-2732.	
	R4	MACK, D.H. *et al.* "Hepatitis B Virus Particles Contain a Polypeptide Encoded by the Largest Open Reading Frame: A Putative Reverse Transcriptase" *J. Virology*, December 1988, 62(12):4786-4790.	
	R5	PASEK, M. *et al.* "Hepatitis B virus genes and their expression in *E. coli*" *Nature*, December 6, 1979, 282:575-579.	
	R6	REDDY, R. *et al.* "In Vivo Cytotoxic T Lymphocyte Induction with Soluble Proteins Administered in Liposomes" *J. Immunology*, March 1, 1992, 148(5):1585-1589.	
	R7	YSSEL, H. *et al.* "T Cell Activation-Inducing Epitopes of the House Dust Mite Allergen *Der p I*" *J. Immunology*, February 1, 1992, 148(3):738-745.	
	R8		
	R9		
	R10		
	R11		
	R12		
	R13		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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DOCKET NO.: EPI-T101D4

August 25, 2003

SERIAL NO.: 09/863,054

DATE FILED: May 21, 2001

APPLICANT : Francis V. Chisari

SUBMISSION TO PTO:

1. Supplemental Information Disclosure Statement
2. Form PTO/SB/08 (2 page); copies of cited references

AUG 30

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AUG 27 2003
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